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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,576	11/06/2000	Charles L. Magness	55382-3	9656

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EXAMINER	
COLON, CATHERINE M	
ART UNIT	**PAPER NUMBER**
3623	

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/707,576	MAGNESS ET AL.	
	Examiner	Art Unit	
	C. Michelle Colon	3623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,14-26,28 and 31-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,14-26,28 and 31-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a Final Office Action in response to the communication received on September 13, 2004. Claims 11-13, 27, 29 and 30 have been cancelled. Claims 47-55 have been added. Claims 1, 15, 19, 20, 28, 31-33 and 41 have been amended. Claims 1-10, 14-26, 28 and 31-55 are now pending in this application.

Response to Amendment

2. Applicant's amendments of claims 1, 15, 19, 20, 28, 31-33 and 41 are acknowledged. The amendments to the claims are sufficient to overcome the 35 U.S.C. 101 technological arts rejection set forth in the previous Office Action; therefore the 35 U.S.C. 101 rejection of claims 1-40 is withdrawn.

Claim Objections

3. Claim 1 is objected to because of the following informalities: Claim 1 recites classifying a population into a sub-population defined as being ARA ***and*** ARU. It is not clear if the use of the word, "and," is correct, or if it is more appropriate for the claim to recite defining a sub-population as being ARA ***or*** ARU, as it does not appear that a sub-population can be classified as being ARA and ARU at the same time. Appropriate clarification is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-10, 14-26, 28 and 31-55 are rejected under 35 U.S.C. 102(a) as being anticipated by well known breast cancer screening methods established by the National Institutes of Health (NIH). The NIH, which includes the National Cancer Institute (NCI), has long conducted clinical trials and studies on populations to determine genetic as well as other types (i.e., familial, environmental, etc.) of risk factors for developing breast cancer. Additionally, the NIH has established various models, such as the Gail Model, for scoring the various risk factors of breast cancer. The following articles will be used to described the well known breast cancer screening methods established by the NIH:

- "Susceptibility to Breast Cancer," Clinical Study started on February 8, 2000 (referred to hereinafter as reference A),
- "Genetic Testing for Breast Cancer Risk: It's Your Choice," August 14, 1997 (referred to hereinafter as reference B),
- "Risk Communication in Clinical Practice: Putting Cancer in Context," 1999 (referred to hereinafter as reference C),

- "Validation Studies for Models Predicting the Risk of Invasive and Total Breast Cancer Incidence," September 15, 1999 (referred to hereinafter as reference D), and
- Archived version of the National Cancer Institute's Breast Cancer Risk Assessment Tool, June 20, 2000 (referred to hereinafter as reference E).

As per claim 1, NIH discloses a computer-implemented method for the identification of a target associated with a selected biological condition, comprising:

using a computer to analyze stored data related to medical histories of a population (reference A, pages 1-2; reference C, pages 2 and 7; reference E, pages 1-7; NIH analyzes medical histories and tests of individuals using a computer model known as the Gail model to determine the risk status of the individuals for developing breast cancer.);

using a computer to analyze stored data related to medical test results for the population (reference A, pages 1-2; reference C, pages 2 and 7; reference E, pages 1-7; NIH analyzes medical histories and tests of individuals using a computer model known as the Gail model to determine the risk status of the individuals for developing breast cancer.); and

based on computer analysis of the data related to the medical histories and the data related to the medical test results, classifying the population into phenotypic sub-population defined as

having a current risk exposure denoted as at risk and affected (ARA) by the selected biological condition (reference A, pages 1and 2; NIH conducted a clinical study that classified people as being at risk and having breast cancer and being at risk and not having breast cancer.), and

having a current risk exposure denoted as at risk and unaffected (ARU) by the selected biological condition (reference A, pages 1and 2; NIH conducted a clinical study that classified people as being at risk and having breast cancer and being at risk and not having breast cancer.);

performing a computer analysis of genetic data from the ARA sub-population and the ARU sub-population to identify genetic variations between the ARA sub-population and the ARU sub-population to identify the target associated with the selected biological condition (reference A, page 1; Part of the goal of the NIH's clinical trial was to determine gene variations between people with breast cancer and people without it.).

As per claim 2, NIH discloses the method of claim 1, further comprising generating statistical data related to the medical histories and the medical test results wherein classifying the population comprises analyzing the statistical data (reference E, pages 1 and 4-7; The Breast Cancer Risk Assessment Tool applies statistical analyses to provide the individual with statistical data representing their risk for developing breast cancer.).

As per claim 3, NIH discloses the method of claim 1, wherein analyzing medical histories comprises assigning numerical scores to selected conditions associated with the selected biological condition (reference E, pages 1-7; reference C, pages 2 and 7;

reference D, page 2; The Breast Cancer Risk Assessment Tool uses the Gail model, which assigns scores and conducts statistical analyses to provide results representing an individual's risk for developing breast cancer.).

As per claim 4, NIH discloses the method of claim 1, wherein analyzing medical test results comprises assigning numerical scores to selected medical tests associated with the selected biological condition (reference E, pages 1-7; reference C, pages 2 and 7; reference D, pages 2 and 14-24; The Breast Cancer Risk Assessment Tool uses the Gail model, which assigns scores and conducts statistical analyses to provide results representing an individual's risk for developing breast cancer.).

As per claim 5, NIH discloses the method of claim 1, wherein analyzing medical histories and medical test results comprises assigning numerical scores to selected conditions associated with the selected biological condition and analyzing medical test results comprises assigning numerical scores to selected medical tests associated with the selected biological condition (reference E, pages 1-7; reference C, pages 2 and 7; reference D, pages 2 and 14-24; The Breast Cancer Risk Assessment Tool uses the Gail model, which assigns scores and conducts statistical analyses to provide results representing an individual's risk for developing breast cancer.).

As per claims 6 and 7, NIH discloses the method of claim 5, wherein classifying the population comprises evaluating the numerical scores for the medical histories and the medical test results; and combining the numerical scores for the medical histories and the medical test results and classifying the population based on the combined

scores (reference A, page 2; The NIH clinical study classifies three groups of participants based on their Gail Model Score.).

As per claims 8 and 9, NIH discloses the method of claim 5, further comprising generating statistical data related to the numerical scores for the medical histories and the medical test results wherein classifying the population comprises analyzing the statistical data; and where the statistical data comprises generating a frequency distribution plot related to the numerical scores for the medical histories and the medical test results (reference D, page 2; The Gail model utilizes an interactive computer program and graphic approaches to represent breast cancer risk.).

As per claim 10, NIH discloses the method of claim 1, further comprising comparing the medical histories and the medical test results of the sub-population classified as ARU with the medical histories and the medical test results of the sub-population classified as ARA (reference A, pages 1 and 2; reference C, pages 2 and 7; reference E, pages 1-7; NIH analyzes medical histories and tests of individuals using a computer model known as the Gail model to determine the risk status of the individuals for developing breast cancer. The NIH uses the data to classify individuals into three groups.).

As per claim 14, NIH discloses the method of claim 1, further comprising selecting the portion of the sub-population classified as ARA and using the selected portion as a control group (reference A, page 2; A control group is determined in the clinical study.).

As per claim 15, NIH discloses the method of claim 1, wherein classifying the population further comprises classifying the population into the ARA sub-population, the ARU sub-population or a phenotypic sub-population defined as unknown risk and unaffected (URU) by the selected biological condition (reference A, pages 1and 2; reference E, pages 8-10; The Breast Cancer Risk Assessment Tool allows for answers including "unknown." Thus, individuals who answer questions using "unknown" cannot have their medical histories and tests analyzes, thus making their risk of breast cancer unknown. NIH conducted a clinical study that classified people as being at risk and having breast cancer and being at risk and not having breast cancer.).

As per claims 16-18, NIH discloses the method of claim 15, further comprising comparing the medical histories and the medical test results of the sub-population classified as ARU with the medical histories and the medical test results of the sub-population classified as URU; and wherein the medical test results comprises genetic test results and comparing the genetic test results of the sub-population classified as ARU with the genetic test results of a selected portion of the sub-population classified as URU; and determining genetic differences between genetic test results of the sub-population classified as ARU with the genetic test results of the sub-population classified as URU (reference A, pages 1 and 2; reference C, pages 2 and 7; reference E, pages 1-7; NIH analyzes medical histories and tests of individuals using a computer model known as the Gail model to determine the risk status of the individuals for developing breast cancer. The NIH uses the data to classify individuals into different groups. The clinical study then compares the genetic differences between the groups.).

As per claim 19, NIH discloses the method of claim 18, further comprising identifying drug targets based on the genetic differences between genetic test results of the sub-populations classified as ARU with the genetic test results of the sub-population classified as URU (reference B, pages 1, 2 and 4; The NCI discloses chemoprevention, a combination of drugs such as tamoxifen and nutrients, for use in patients whose genetic tests reveal mutations of the BRCA1 and BRCA2 genes, as genetic tests have revealed the presence of altered BRCA1 and BRCA2 genes in people significantly increases their risk of developing breast cancer.).

As per claims 47-50, NIH discloses the method of claim 1 wherein identifying a target comprises identifying a drug target, diagnostic assay, vaccine and drug component based on the genetic variations between genetic test results of the group of subjects classified as ARU with the genetic test results of the group of subjects classified as ARA (reference B, pages 1-4; The NCI discloses various options to manage cancer risk in subjects whose genetics tests revealed the presence of altered BRCA1 and BRCA2 genes, which indicates a significantly increased risk of developing breast cancer. The various options include chemoprevention, a combination of drugs such as tamoxifen and nutrients, surveillance assays such as mammographies and clinical breast exams, and prophylactic surgery.).

Claims 20-26, 28, 31-46 and 51-55 recite substantially similar subject matter as claims 1-10, 14-19 and 47-50 above. Therefore, claims 20-26, 28, 31-46 and 51-55 are rejected on the same basis as claims 1-10, 14-19 and 47-50 above.

Response to Arguments

6. Applicant's arguments are moot in view of the new grounds of rejections.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Diehl et al. (U.S. 6,130,042) discusses conducting genetic tests for diagnosing periodontal disease;

- Skolnick et al. (U.S. 5,753,441) discusses gene mutations indicative of a predisposition to breast cancer;
- Blumenfeld et al. (U.S. 5,387,506) discusses genetic markers to diagnose familial dysautonomia;
- Hudson, Thomas "The human genome project: Tools for the identification of disease genes," *Clinical and Investigative Medicine*, Dec 1998, [retrieved from Proquest] discusses analyzing genetic variations among individuals including mutations that cause diseases;
- Khoury, Muin. "From genes to public health: The applications of genetic technology in disease prevention," *American Journal of Public Health*, Dec 1996, [retrieved from Proquest] discusses genetic analyses for disease genes;
- Hunter, David. "The future of molecular epidemiology," *International Journal of Epidemiology*, Oct 1999, [retrieved from Proquest] discusses high-penetrance and low-penetrance genes and diseases;
- Wade, Nicholas. "DNA chips join anti-cancer fight Devices monitor genetic mutations," *Denver Post*, Apr 8, 1997, [retrieved from Proquest] discusses chips that measure gene expression and detect mutations;
- Emilien et al. "Impact of genomics on drug discovery and clinical medicine," Jul 2000, [retrieved from Internet] discusses defining populations genetically could improve responses to drugs;

- Sharp et al. "Involving study populations in the review of genetic research," The *Journal of Law, Medicine & Ethics*, Spring 2000, [retrieved from Proquest] discusses genetic dispositions of people;
- Chow et al. "Effect of Tamoxifen on Mammographic Density," September 2000, [retrieved from Internet] discusses the effect of tamoxifen on breast cancer;
- Slattery et al. "A comprehensive evaluation of family history and breast cancer risk." Oct 6, 1993, [retrieved from Internet] discusses breast cancer risks;
- Rosenthal et al. "Screening for Genetic Risk of Breast Cancer," January 1, 1999, [retrieved from Internet] discusses genetic risks for breast cancer;
- Spiegelman et al. "Validation of the Gail et al. model for predicting individual breast cancer risk." Apr 20, 1994, [retrieved from Internet] discusses the Gail model for assessing breast cancer risk;
- Holtzman et al. "Final Report of the Task Force on Genetic Testing," September 1997, [retrieved from Internet] discusses standards established by the government for genetic testing;
- "New Genetic Mutation Linked To Breast Cancer," *Doctor's Guide*, August 31, 1998, [retrieved from Internet] discusses the genetic mutations of breast cancer;
- Colditz et al. "Family history, age, and risk of breast cancer." Jul 21, 1993 [retrieved from Internet] discusses various factors of breast cancer risk.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Michelle Colon whose telephone number is 703-605-

4251. The examiner can normally be reached Monday – Friday from 8:30am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tariq Hafiz, can be reached at 703-305-9643.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks

Washington D.C. 20231

or faxed to:

703-872-9306	[Official Communications; including After Final communications labeled "Box AF"]
703-746-7202	[For status inquiries, draft communication, labeled "Proposed" or "Draft"]

Hand delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA 7th floor receptionist.

cmc
December 16, 2004

TARIQ R. HAFIZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600